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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,134	11/18/2003	Ling Yuk Cheung	KONG-20	7258
1473	7590	06/20/2006	EXAMINER	
FISH & NEAVE IP GROUP ROPES & GRAY LLP 1251 AVENUE OF THE AMERICAS FL C3 NEW YORK, NY 10020-1105			SRIVASTAVA, KAILASH C	
			ART UNIT	PAPER NUMBER
			1655	

DATE MAILED: 06/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/717,134

Applicant(s)

CHEUNG, LING YUK

Examiner

Dr. Kailash C. Srivastava

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-12 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The Art Unit Location for your application under prosecution at the United States Patent and Trademark Office (i.e., USPTO) has been changed to Art Unit 1655. To aid in correlating any papers for this application (i.e., 10/717,134), all further correspondence regarding this application should be directed to Examiner Kailash C. Srivastava in Art Unit 1655.

Claims Status

2. Claims 1-12 are pending.

Election/Restriction

3. Restriction to one of the following inventions is required under 35 U.S.C. §121:

- Group I – Encompassing Claims 1-5 and 8 drawn to a composition comprising a plurality of yeast cells belonging to yeast genera *Rhodotorula*, *Saccharomyces* and *Schizosaccharomyces* activated via exposing said yeast cells to electromagnetic fields of different frequency and field strength, wherein said composition treats discoid, drug-induced, neonatal or systemic lupus erythematosuses, classified under Class 435, Subclass 171, for example.
- Group II–Encompassing Claims 6-7 drawn to a pharmaceutical composition comprising a plurality of yeast cells belonging to yeast genera *Rhodotorula*, *Saccharomyces*, or *Schizosaccharomyces* activated via exposing said yeast cells to electromagnetic fields of different frequency and field strength and then packaging them as a tablet or health drink, classified under Class 424, Subclass 439, for example.
- Group III- Encompassing Claims 9-10 drawn to a method to prepare a composition via culturing a plurality of yeast cells under exposure to electromagnetic fields of different frequencies and field strength ranges, classified under Class 435, Subclass 195.16, for example.
- Group IV- Encompassing Claims 11-12 drawn to a method to treat lupus erythematosus comprising orally administering to an individual in need thereof a

composition comprising a plurality of activated yeast cells that have been activated via exposing said yeast cells to electromagnetic fields of different frequency and field strength, classified under Class 435, subclass 255.1 or 255.2, for example.

Inventions are Independent Or Distinct

4. The inventions are distinct, each from the other because of the following reasons:

Inventions in Groups I-II are related to each other as sub-combinations disclosed as usable together in a single combination. The sub-combinations are distinct from each other if they are shown to be separately usable. In the instant case, an invention in Groups I-II has separate utility. For example invention in Group II is a mixture of electromagnetically activated yeast with a beverage or a pharmaceutical carrier. The invention ascribed to Group I on the other comprises activated yeast cells treated with electromagnetic fields of different frequencies and strengths. This means the composition of each one of inventions encompassing claims in each of Groups can function independent of each other as a mere supplement to any composition, while composition in Group II would still function as a pharmaceutical or a dietary supplement.

Inventions in Groups I-II are related to invention in Group III as products made and process of making said product. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the claimed method to prepare said composition may also be used to prepare any chemical or a fertilizer. Likewise, the claimed composition may also be prepped by other fermentation and mixing means, e.g., mutating yeasts with art-known mutants to advance their physiological properties and then mixing them with art-known ingredients to concoct them in to a pharmaceutical or a dietary supplement.

Inventions in Groups I-II are related to invention in Groups IV as product and use thereof. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product [MPEP § 806.05(h)]. The process of treating lupus

erythematosus may also be achieved with a number of prescription treatments/ drugs that are readily available to an individual in need of when under a medical professional's care and supervision.

Method inventions in Groups III-IV are not connected in design, operation, and/or effect. These methods are independent since they are not disclosed as capable of use together, they have different modes of operation, they have different functions, and/or they have different effects. One would not have to practice the various methods at the same time to practice just one method alone.

The several inventions above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each one of the above inventions is not coextensive particularly with regard to the literature search. For example the strategy for searching the invention in Group I will require incorporation of only electromagnetic force and yeasts, whereas one in Group II would additionally require a pharmaceutical carrier or beverage. Likewise, the search strategy for the invention in Group III would require the key words lupus, lupus erythematosus, or immune response disease that will not be required to search invention in Group II. Further, a reference that would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and their recognized diverse subject matter, restriction for examination purposes as indicated is proper.

Species Election

5. This application contains claims directed to different compositions comprised of a variety of ingredients. Said compositions are comprised of single ingredient (s) or mixtures of ingredients (e.g., yeasts of different genera and species grown under a variety of culture conditions).

The search for each of the above inventions is not co-extensive, particularly with regard to the literature search. This is because of the fact that the inventive groups

discussed above incorporate numerous compositions and numerous ingredients within each of the same, single composition. For example, to conduct a literature search for invention in Group I that is constituted of different yeast genera and species along with the different electromagnetic force frequencies and field strength, one would be searching for a total number of combinations that will be a factorial of at least 23 with each one of the ingredients up to ingredient number 1 (i.e. 23×22 , 23×21 , 23×20 , 23×19 , 23×18 ---- 23×1). Thus, this group alone will exert an enormous search burden on the Examiner. Additional groups will be frequencies in the range of 9,500 MHz-18, 500 MHz, field strengths in range of 250mV/cm^2 - 520mV/cm^2 and permutations of each of the variables listed above. The sum total of all the groups will be a number of geometrical proportions. Therefore, if the applicant elects any one of Groups I-IV above, the applicant must also make election of species by electing a single species from each of the following categories:

- a. One frequency range in claims 1-2 and 9-10;
- b. One field strength in claims 1 and 3;
- c. One yeast genus among *Rhodotorula*, *Saccharomyces* or *Schizosaccharomyces* claimed in Claims 4-5; and
- d. One type of Lupus erythematosus among discoid, drug-induced, neonatal or systemic listed in Claim 8.

For example if the applicant elects for prosecution the method of Claim Group III, the applicant election statement should be. For e.g., "Applicant elects the invention in Group III to a method of making a composition comprising yeast exposed to a frequency ranging 9,500 MHz-18, 500 MHz, field strengths in range of 250mV/cm^2 - 520mV/cm^2 , wherein the yeast is *Saccharomyces uvarum* and the lupus erythematosus is discoid lupus erythematosus.

6. If applicant elects any one of Groups I-IV, the applicant is required under 35 U.S.C. §121 to elect a single disclosed species of composition, enumerating all ingredients therein for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1, 9 and 11 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is

allowable or that all claims are generic is considered non-responsive unless accompanied by an election. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR §1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species [MPEP § 809.02(a)].

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR §1.48(b) if one or more of the currently named inventors are no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR §1.48(b) and by the fee required under 37 CFR §1.17(I).

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR §1.116; amendments submitted after allowance are governed by 37 CFR §1.312.


In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR §1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. §101, §102, §103, and §112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to**


rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. §121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP §804.01.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Terry McKelvey, can be reached on (571)-272-0775 Monday through Friday 8:30 A.M. to 5:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). Alternatively, status inquiries should be directed to the receptionist whose telephone number is (703) 308-0196.


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